

Atty. Dkt. No. 071949-2104

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Buechler, et al.

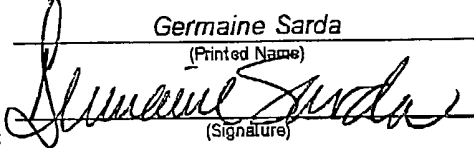
Title: NOVEL METHODS FOR THE ASSAY
OF TROPONIN I AND T AND
COMPLEXES OF TROPONIN I AND T
AND SELECTION OF ANTIBODIES
FOR USE IN IMMUNOASSAYS

Appl. No.: 09/349,194

Filing Date: 06/07/1999

Examiner: Gailene Gabel

Art Unit: 1641

CERTIFICATE OF FACSIMILE TRANSMISSION I hereby certify that this paper is being facsimile transmitted to the United States Patent and Trademark Office, Alexandria, Virginia on the date below.
<u>Germaine Sarda</u> (Printed Name)
<u></u> (Signature)
<u>November 29, 2004</u> (Date of Deposit)

TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed please find the following:

[X] Appendix A: Clean Copy Text of the Claims as Amended in Submission Dated
07/07/2003 (14 Pages).

Respectfully submitted,

Date November 29, 2004By 

FOLEY & LARDNER LLP
Customer Number: 30542
Telephone: (858) 847-6722
Facsimile: (858) 792-6773

Barry S. Wilson
Attorney for Applicant
Registration No. 39,431

*Appendix A: Clean Copy Text of the Claims as Amended in Submission Dated July 7, 2003
(claims identified as "previously amended" were amended on July 7, 2003)*

1-84 (cancelled)

85. (Previously pending) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising: performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a binary complex comprising one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac specific isoform of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoform of troponin in said sample.

86. (Previously pending) An assay according to claim 85, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

87. (Previously pending) An assay according to claim 85, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii).

88. (Previously pending) An assay for determining the presence or amount of free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I and cardiac specific troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds to cardiac specific troponin I and cardiac specific troponin T in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoforms of troponin in said sample.

89. (Previously pending) An assay according to claim 88, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

90. (Previously pending) An assay according to claim 88, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoforms of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoforms of troponin; or (iii) a combination of (i) and (ii).

91. (Previously pending) An assay for determining the presence or amount of free and complexed cardiac specific troponin I in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin I, and which specifically binds to cardiac specific troponin I in a complex comprising at least one other troponin component selected from the group consisting of troponin C and troponin T, and which specifically binds to cardiac specific troponin I in a ternary complex comprising troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin I in said sample.

92. (Previously pending) An assay according to claim 91, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

93. (Previously pending) An assay according to claim 91, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin I is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin I; (ii) troponin complexes which do not comprise said cardiac specific troponin I; or (iii) a combination of (i) and (ii).

94. (Previously pending) An assay for determining the presence or amount of free and complexed cardiac specific troponin T in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds to free cardiac specific troponin T, and which specifically binds to cardiac specific troponin T in a complex comprising at least one other troponin component selected from the group consisting of troponin

C and troponin I, and which specifically binds to cardiac specific troponin T in a ternary complex comprising troponin C and troponin I; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii), and wherein said detectable signal is related to the presence or amount of said free and complexed cardiac specific troponin T in said sample.

NOV. 29. 2004 11:35AM FOLEY 8587926773

95. (Previously pending) An assay according to claim 94, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

96. (Previously pending) An assay according to claim 94, wherein said signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific troponin T is at least a factor of five greater than said signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific troponin T; (ii) troponin complexes which do not comprise said cardiac specific troponin T; or (iii) a combination of (i) and (ii).

97-101 (cancelled)

102. (Previously pending) An assay for determining the presence or amount of all free and complexed cardiac specific isoforms of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds all free cardiac specific isoforms of troponin, and which specifically binds all cardiac specific isoforms of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds all cardiac

specific isoforms of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and

detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoforms of troponin, wherein said signal is related to the presence or amount of all free and complexed cardiac specific isoforms of troponin in said sample.

103. (Previously pending) An assay according to claim 102, wherein said patient sample is selected from the group consisting of a blood sample, a serum sample, and a plasma sample.

104. (Previously pending) An assay according to claim 102, wherein said signal is approximately equal for equal amounts of all cardiac specific isoforms of troponin.

105. (Previously pending) An assay according to claim 102, wherein said signal is within 20% for equal amounts of all cardiac specific isoforms of troponin.

106. (Previously pending) An assay according to claim 102, wherein said signal is within a factor of 2 for equal amounts of all cardiac specific isoforms of troponin.

107-113 (cancelled)

114. (Previously pending) An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising:

performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a complex comprising at least one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac

**FOLEY & LARDNER LLP
ATTORNEYS AT LAW**

11250 EL CAMINO REAL, SUITE 200
SAN DIEGO, CA 92130
P.O. BOX 80278
SAN DIEGO, CA 92138-0278
TELEPHONE: 858.847.6700
FACSIMILE: 858.792.6773
WWW.FOLEY.COM

FACSIMILE TRANSMISSION**Total # of Pages 16 (including this page)**

TO:	PHONE #:	FAX #:
Ms. Diane Maggard United States Patent and Trademark Office Board of Patent Appeals and Interferences		571-273-0300

From : Barry S. Wilson**Date :** November 29, 2004**Client/Matter No :** 071949-2104**User ID No :** 3067**MESSAGE:**

Re: U.S. Patent Application No. 09/349,194
Our Ref.: 071949-2104

Per your request please find the enclosed documents:

- Transmittal (1 pg.);
- Appendix A: Clean Copy Text of the Claims as Amended in Submission Dated 07/07/03 (14 pgs.).

If there are any problems with this transmission or if you have not received all of the pages, please call 858.847.6700.

Operator:**Time Sent:****Return Original To:**
Germaine Sarda

CONFIDENTIALITY NOTICE: THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENTS NAMED ABOVE. THIS MESSAGE MAY BE AN ATTORNEY-CLIENT COMMUNICATION, AND AS SUCH IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR ANY AGENT RESPONSIBLE FOR DELIVERING IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISSEMINATION, DISTRIBUTION OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.